# 510(K) Summary of Substantial Equivalence

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| Date prepared | July 2, 2001 |
| Submitter: | Medtronic, Inc.<br>7000 Central Avenue N.E.<br>Minneapolis, MN 55432 |
| Contact: | Karen Reidt, RAC<br>Sr. Product Regulation Manager |
| Telephone: | (763) 514-3914 |
| Fax: | (763) 514-6424 |
| E-Mail: | karen.reidt@medtronic.com |
| Proprietary Name: | Attain™ Access 6218 Left-heart delivery system |
| Common Name: | Catheter, Percutaneous |
| Device Classification: | Class II, 21 CFR § 870.1250 |
| Product Code: | 74 DQY |

## Device Description

The left-heart delivery system features two guide wires to facilitate venous access, an adjustable hemostasis valve to reduce blood loss during the implant procedure, two guide catheters for passing venogram balloon catheters or appropriate leads, a guide catheter dilator to facilitate guide catheter passage, guide catheter slitters for removing guide catheters, and a guide wire clip to help contain the guide wire in the sterile field.

A steerable 7 French or smaller intracardiac catheter is recommended for use to assist in placing guiding catheters to access cardiac veins via the coronary sinus. The Attain Access 6218 is intended for single use only and will be distributed independently for use with current and future leads.

The Attain Access Model 6218 combines components that are either cleared for market distribution via 510(k) or are exempt from premarket notification because of Class I designation.

## Indications for Use

The intended use of the Medtronic Attain Access 6218 Left-heart delivery system is for introducing balloon catheters into the coronary sinus or leads into vessels of the left heart via the coronary sinus

## Substantially Equivalent Devices

**Attain Access 6218 Left-heart Delivery System Predicate Devices**

| Attain Access Model 6218 Left-heart Delivery System Device | Predicate Device | Predicate Device Manufacturer | Predicate 510(k) |
|---|---|---|---|
| 45 cm and 50 cm Guide Catheters | Medtronic GC IV Coronary Guiding Catheter | Medtronic Interventional Vascular (MIV) Danvers, MA 01923 | K950490 |
| | SafeSheath MSP (Same as SafeSheath CSG) | Thomas Medical Malvern, PA 19355 | K003731 |
| | GC III (Vector, Vector X) Coronary Guiding Catheter | Medtronic Interventional Vascular (MIV) Danvers, MA 01923 | K950179 |
| | Zuma Guiding Catheter | Medtronic Interventional Vascular (MIV) Danvers, MA 01923 | K990707 |
| Guide Catheter Dilator | Percutaneous Introducer Kit (Component) | MedAmicus Minneapolis, MN 55447 | K965167 |
| | SafeSheath MSP (Same as SafeSheath CSG) | Thomas Medical Malvern, PA 19355 | K003731 |
| Adjustable Hemostasis Valve | Y-Adaptor W/Touhy Borst Valve | Angeion Corp Plymouth, MN 55441 | K895580 |
| 120 cm Guide Wires | TFX Medical Guide Wire | TFX Medical Group Jaffrey, NH 03452 | K963320 |
| 4 Fr and 6 Fr Guide Catheter Slitters | Percutaneous Introducer Kit (Component) | MedAmicus Minneapolis, MN 55447 | K965167 |
| Guide Wire Clip | Class I device, exempt from premarket notification | | |

## Summary of Studies

Compatibility Testing, incoming inspection of final packaged device and package qualification testing was performed to support substantial equivalence to the predicate devices. Attain Access passed all of the *in vitro* specified requirements, and ensures that the Attain Access 6218 meets all of its design and performance requirements.

The Attain Access 6218 was included in two (2) Medtronic sponsored IDE clinical studies to facilitate the implantation of left ventricular leads. The Attain Access 6218 Left-heart delivery system has performed as expected in the clinical environment during venogram imaging, and left ventricular lead placement via the coronary sinus.

## Biocompatibility Information

Biocompatibility testing was performed on the materials which are blood contacting. Complete testing according to ISO 10993-1 was conducted and all materials were found to be biocompatible.

## Sterilization Validation

The Attain Access 6218 Left-heart delivery system is sterilized using a 100% Ethylene Oxide (ETO) sterilization process. Appropriate processes for sterilizing the devices were validated.

## Conclusion

Through the data and information presented, as well as similarities to legally marketed devices, Medtronic Inc, considers the Attain Access 6218 Left-heart delivery system to be substantially equivalent to the previously discussed legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 8 2001

Ms. Karen Reidt
Medtronic, Inc.
Cardiac Rhythm Management
7000 Central Avenue NE
Minneapolis, MN 55432-3576

Re: K012083
Trade Name: Attain Access 6218 Left-Heart Delivery System
Regulation Number: 21 CFR 870.1250
Regulatory Class: Class II (two)
Product Code: 74 DQY
Dated: July 2, 2001
Received: July 3, 2001

Dear Ms. Reidt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): ~~N/A~~ K012083

Device Name: Attain™ Access 6218 Left-heart delivery system

Indications For Use: The Attain Access 6218 Left-heart delivery system is intended for introducing balloon catheters into the coronary sinus or leads into vessels of the left heart via the coronary sinus.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012083